K072391 (2 / 2)

510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Name: PFM Medical, Inc

Address: 2605 Temple Heights Drive
Suite A
Oceanside, CA 92056

CONTACT PERSON: SALVADORE F. PALOMARES, RAC

NOV 19 2007

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:
Trade Name: PFM PICC
Common Name: Catheter, Intravascular, Therapeutic, Long Term
Classification: LJS

Equivalent Devices:
Manufacturer: MedComp
Name: PRO-LINE CT Power Injectable CVC
510(k) #: K053345

Device Description:
The PFM Medical PFM PICC Catheters are designed for central venous catheterization. The PFM PICC lumen is comprised of a soft radiopaque polyurethane material. The lumen is connected to the extensions via a soft pliable hub with suture wing for secure placement. Cuff attachment to the lumen provides for tissue ingrown. Clamps are provided on the extension tubes to prevent air/fluid communication. Female luer connectors provide the connection for intravenous administration.
The catheters are available in 3F, 4F, 5F and 6F single lumen versions, and 4F, 5F and 6F in double lumen versions. The catheters are up to 60 cm in length with depth markings in 5 cm increments. Stylet and adaptor sideport is provided to assist in catheter insertion.
The catheters can be used in the injection of contrast media. The maximum recommended infusion rate is 5 cc/sec. The maximum pressure of power injectors used with the PFM PICC catheter may not exceed 300psi
The PFM PICC product line is packaged with the necessary accessories for a percutaneous microintroducer introduction (Modified Seldinger or Seldinger technique).

Intended Use:
The PFM PICC is indicated for short or long term access to the central venous system. It is designed for administering IV fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal and power injection of contrast media. The maximum recommended infusion rate is 5 cc/sec. The maximum pressure of power injectors used with the PFM PICC may not exceed 300 psi.

K073391 (2/2)

Performance Data:
In vitro testing was performed on the PFM PICC to assure reliable design and performance in accordance with ISO 10555-1 and 105553. Testing includes air/liquid leakage, cuff shear, force at break, elongation, gravity flow, static burst pressure, high pressure injection flow rate and chemical testing.

Clinical studies were not deemed necessary since in vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate device.

Biocompatibility:
Biocompatibility testing on the PFM PICC demonstrates that the materials used meet the requirements of ISO 10993 for a permanent contact device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2007

Mr. Salvadore F. Palomares, RAC
Director of Regulatory Affairs
PFM Medical, Incorporated
2605 Temple Heights Drive, Suite A
Oceanside, California 92056

Re: K072391
Trade/Device Name: PFM PICC
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: October 15, 2007
Received: October 16, 2007

Dear Mr. Palomares:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

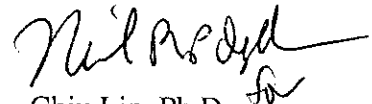
Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k):

Device Name: **PFM PICC**

Indications for Use: The PFM PICC is indicated for short or long term access to the central venous system. It is designed for administering IV fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal and power injection of contrast media. The maximum recommended infusion rate is 5 cc/sec. The maximum pressure of power injectors used with the PFM PICC may not exceed 300 psi.

Prescription Use ___X_____ AND/OR Over the Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K973391